Robert H. Roswell, M.D. Under Secretary for Health Department of Veterans Affairs Washington, DC 20420

SUBJECT: NRC INSPECTION REPORT (IR 030-34325/2004-002(DNMS))

Dear Dr. Roswell:

This refers to the announced team inspection conducted on March 2 through 4, 2004. The purpose of the inspection was to review the activities authorized under the Department of Veterans Affairs (DVA) Master Materials License (MML), and the inspection is the second comprehensive semi-annual NRC inspection of DVA activities, covering the period from September 22, 2003 through March 4, 2004. At the conclusion of the inspection on March 4, 2004, the NRC's findings were discussed with Thomas Holohan, M.D., Chairman, DVA MML National Radiation Safety Committee, and with the DVA's National Health Physics Program staff.

The NRC is implementing a program of increased oversight of the DVA, which includes semi-annual inspections of the DVA's MML program over a two-year period. Each semi-annual inspection involves an evaluation of MML activities conducted by the DVA over a six-month period.

This semi-annual inspection consisted of an examination of activities conducted under your MML as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the MML. Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations of activities in progress, and interviews with personnel.

Based upon the inspection, no violations of NRC requirements were identified. The NRC determined that the DVA implemented its MML in accordance with NRC licensing and inspection policies and procedures, and that, overall, the DVA is implementing its permitting and inspection programs in a manner that protects public health and safety. The inspection team also confirmed that the DVA took appropriate action to address two issues that were identified by an NRC inspection team during the first semi-annual inspection conducted in September 2003. The two issues pertained to updating standard operating procedures and informing the DVA's National Radiation Safety Committee of an allegation that was being processed by the National Health Physics Program.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The ADAMS system is accessible from the NRC Web site at <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a> (the Public Electronic Reading Room).

R. Roswell -2-

We will gladly discuss any questions you have concerning this inspection.

Sincerely

/RA/

Marc L. Dapas, Director Division of Nuclear Materials Safety

Docket No.: 030-34325 License No.: 03-23853-01VA

Enclosure: NRC Inspection Report No. 030-34325/2004-002(DNMS)

cc w/encl: E. Lynn McGuire, Director

DVA National Health Physics Program

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#### **U. S. NUCLEAR REGULATORY COMMISSION**

**REGION III** 

Docket No.: 030-34325

License No.: 03-23853-01VA

Report No.: 030-34325/2004-002(DNMS)

Licensee: Department of Veterans Affairs (DVA)

Location: National Health Physics Program

Little Rock, Arkansas

Inspection Dates: March 2 - 4, 2004

Inspectors: Kevin G. Null, Senior Health Physicist and

Project Manager for DVA Master Materials License

(MML), Region III

Ujagar S. Bhachu, Mechanical Engineer and

**MML Project Coordinator** 

NMSS/IMNS

Anthony D. Gaines, Senior Health Physicist

Region IV

Toye Simmons, Health Physicist

Region III

Approved by: John Madera, Chief

Materials Licensing Branch

Division of Nuclear Materials Safety

Region III

## **EXECUTIVE SUMMARY**

**Department of Veterans Affairs Master Materials License** 

## NRC Inspection Report No. 030-34325/2004-002

This announced NRC team inspection was conducted to evaluate the Department of Veterans Affairs (DVA) implementation and administration of activities conducted under the Master Materials License (MML). The inspection included an assessment of the DVA's implementation of its centralized control program, an evaluation of the DVA's radioactive materials permitting and inspection programs, a review of the results of Nuclear Regulatory Commission (NRC) inspections of DVA permittee facilities conducted during the six-month assessment period, and an examination of the National Radiation Safety Committee's (NRSC's) oversight of activities authorized by the MML. Licensed activities conducted during the period of September 22, 2003 through March 4, 2004, were reviewed during this inspection.

Through interviews and discussions with DVA staff, evaluation of the DVA's response to an NRC questionnaire, reviews of documents related to MML activities, and observations of DVA staff in the performance of their duties, the NRC inspection team concluded that, overall, the DVA's permitting and inspection programs were adequate and being implemented in a manner that protects the health and safety of workers and the general public.

The program areas assessed during this team inspection are summarized below:

## Management Oversight

The team concluded that the NRSC, through its National Health Physics Program (NHPP) staff, conducted operations in accordance with the MML and associated Letter of Understanding, DVA's Standard Operating Procedures, and NRC regulations. The NRSC was effective in executing its responsibility and provided appropriate oversight of the DVA's radiation safety and regulatory compliance program.

### **Technical Quality of Inspections**

 The team concluded that the NHPP inspectors conducted performance-based inspections in a manner that was consistent with NRC policies and procedures. In addition, the team determined that the DVA's inspection program is compatible with NRC's inspection policies, procedures, and guidelines, and in accordance with the MML.

## Status of Materials Inspection Program

The inspection team concluded that NHPP management appropriately assigned program codes and inspection due dates for its permittees. The NHPP has developed an acceptable plan to complete 17 inspections by the end of calendar year 2004 for those permittees whose required frequency of inspection was reduced from five years to three years when Manual Chapter 2800, "Revised Materials Inspection Program" was revised in November 2003. Notwithstanding this issue, the inspection team determined that all other inspections that were due during this six-month review period were completed in a timely manner.

### Technical Staffing and Training

The inspection team concluded that the DVA has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a master materials licensee. The NHPP has developed a plan to complete its inspector training program by the end of calendar year 2006. The team also concluded that the NHPP has successfully balanced the acquisition and scheduling of staff training and management of the permitting and inspection workload, while successfully implementing a centralized control program.

## Technical Quality of Permitting Program

 The inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures, and guidance. In addition, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

### Status of Permitting Program

 The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures. The process for reviewing and issuing permitting actions by the DVA was efficient, with timely issuances of permitting actions and a zero backlog.

#### Allegation and Incident Handling Programs

- No allegations have been received by the DVA (either via NRC referral or direct receipt from permittee staff or members of the public) during the second semi-annual review period, i.e., since September 2003. The NHPP has completed its investigation of an allegation that was forwarded by the NRC to the NHPP on June 29, 2003. An NRSC working group appointed by the Committee has reviewed the results of the NHPP investigation, and will be making a recommendation to close out the unsubstantiated allegation at the next NRSC meeting scheduled for April 29, 2004. The inspection team concluded that the DVA continues to process the allegation it received from the NRC in June 2003, in accordance with the MML.
- The inspection team concluded that the DVA's program for responding to incidents was in compliance with the MML conditions and applicable NRC regulations and was being implemented effectively. Two medical events were reported during this review period.

## NRC Independent Inspections of DVA permittees

The NRC inspected 14 DVA permittees during the review period. One Severity Level III
and two Severity Level IV violations were identified. Based on the overall results of the
independent inspections conducted by the NRC, the inspection team concluded that
permittee activities were conducted in a manner that protected the health and safety of
its staff and the public.

## **Report Details**

#### 1.0 Program Overview

The Department of Veterans Affairs (DVA) is authorized under NRC Master Materials License (MML) number 03-23853-01VA, to issue byproduct radioactive material permits and inspect DVA medical facilities throughout the United Sates. The DVA oversees approximately 115 permittees. The license was issued on March 17, 2003, and does not have an expiration date.

The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The Committee has delegated the authority to manage the DVA radiation safety program and DVA day-to-day operations to its National Health Physics Program (NHPP), which includes a program director and five program managers who are responsible for issuing permits, conducting inspections, and investigating incidents and allegations.

### 2.0 Management Oversight

#### a. Inspection Scope

The NRC inspection team evaluated the licensee's NRSC organization and management oversight activities to determine whether the Committee and its NHPP office adequately controlled the use of licensed materials, as required by the MML and NRC regulations, in a manner that protects the public health and safety. The assessment included observations of NRSC meetings, a review of notes from quarterly NHPP program managers' meetings, discussions with cognizant licensee representatives, and a review of program documentation, including an internal audit report.

## b. Observations and Findings

The NRSC meets quarterly and is comprised of senior DVA managers and DVA headquarters and field representatives. During the six-month review period, the NRSC met twice. Based on observations by NRC staff in attendance at both meetings and a review of the NRSC minutes, NRC staff confirmed that the Committee met its minimum requirements for establishing a quorum. The NRC Project Manager and Nuclear Materials Safety and Safeguards (NMSS) MML Project Coordinator observed NRSC interaction with NHPP staff and management at both meetings, and confirmed that the Committee was actively engaged in, and effectively provided oversight and direction on, issues raised by the NHPP.

Through NRC attendance at the NRSC's quarterly meetings, observations by NRC staff during their accompaniments of NHPP inspectors, and an evaluation of the results of NRC independent inspections of DVA permittees, the NRC inspection team determined that the NHPP has been effective and timely in communicating important issues to its permittees. Examples include communication of issues related to security, inspection findings of generic interest and applicability, revisions to DVA MML procedures, results of NRC inspections, and NHPP inspection reports and permitting actions. The NHPP relies heavily on electronic forms of communication in transmitting inspection reports, permitting actions, and informational newsletters to permittees. However, the NHPP also communicates directly with permittees via telephone, as necessary.

During the January 29, 2004, NRSC meeting, the Committee and members of the NHPP actively discussed two security violations identified by the NRC. One was identified at the McGuire VA Medical Center, Richmond, Virginia, and the other was identified at Hines VA, Hines, Illinois. The Deputy Under Secretary for Health, accompanied by the Director of Safety, attended the meeting as a result of the recent security findings. Both expressed their concern over the lapse in security at the two institutions and emphasized the importance of making improvements at all levels within the DVA in the areas of prevention and identification of security related problems. As a result, the DVA is exploring ways to assist its permittees in disposing of old, unused sealed sources in storage ("disused sources") and to incorporate additional engineering controls to improve security of licensed material.

In addition, the NHPP and NRSC are analyzing ways to improve: 1) identification of security weaknesses through surveillance by permittee safety/police staff); 2) restricting accessibility to material by unauthorized individuals through the use of two methods to secure material, i.e., keeping material in a locked safe and storing the safe in a locked storage room; and 3) response to breaches in security through coordination with permittee safety/police staff. In addition, as a baseline approach in its efforts to improve security, the NHPP, through delegation given to it by the NRSC, is developing a centralized sealed source inventory program for all sealed sources (used and "disused"). Using documents from the International Atomic Energy Agency and the National Council on Radiation Protection, the NHPP is working with members of the NRSC to draft a definition of a "disused source," which will be provided to all of its permittees.

The NRSC remains committed to delegating authority to the NHPP to manage the DVA's radiation safety program and its day-to-day operations. This includes implementation of the permitting and inspection programs, incident and allegation follow-up responsibilities, obtaining training for staff, and maintaining an acceptable level of staff to execute the program. The NHPP is responsible for six standard operating procedures (SOPs), which are essential in implementing the MML. The SOPs include reference to procedures for processing permits, conducting inspections, taking enforcement action, training inspectors, responding to incidents, and managing allegations. In addition, the NHPP developed and implemented detailed internal procedures that are designed to assure compliance with the SOPs.

During the first semi-annual inspection conducted in September 2003, the team noted that the DVA's SOPs had not been updated to reflect the revised 10 CFR Part 35 issued in October 2002. Any changes to SOPs, including administrative changes, require an amendment to the MML. In the Letter of Understanding (LOU) between the NRC and the DVA, the DVA is required to update its policies and procedures to reflect the most current NRC regulations. The NRC inspection team concluded, however, that even though it had not updated its SOPs, the DVA, through its NHPP staff and DVA permittees, was well aware of the changes and had used the revised 10 CFR Part 35 and related NRC guidance in conducting inspections and issuing permitting actions, as well as to guide permittee activities/operations.

On December 18, 2003, the DVA received an amendment to its MML, which authorized the DVA to make administrative changes to its SOPs without requiring an amendment to the MML. Subsequent to that amendment, the NHPP modified its SOPs to be consistent with the new 10 CFR Part 35. Draft revisions to applicable SOPs were forwarded to the Region III Project Manager for review. Final versions of the SOPs were provided to the inspection team for review during the second semi-annual team

inspection. The inspection team noted that the SOPs were consistent with the new 10 CFR Part 35.

### c. Conclusion

The inspection team determined that the NRSC and NHPP provided adequate oversight of DVA implementation of its MML, and conducted and controlled DVA activities in a manner that assured compliance with the MML, DVA's SOPs, and NRC regulations. The team also concluded that the DVA, through its NRSC and NHPP, demonstrated an acceptable level of centralized control of licensed activities, and maintained a functioning centralized administrative structure.

The inspection team determined that the NHPP adequately addressed issues identified in the September 2003 semi-annual inspection related to the updating of its SOPs to reflect current NRC regulations pertaining to 10 CFR Part 35.

# 3.0 Technical Quality of Inspections

#### a. Inspection Scope

The NRC inspection team reviewed inspection plans, inspection reports, and enforcement documents and correspondence associated with inspections conducted by the NHPP during the review period to determine if NHPP inspections were consistent and in conformity with NRC inspection procedures. In addition, the team interviewed NHPP inspectors to evaluate how they prepared for inspections. This included a review of the permit (or previous NRC license), licensing-related documents, and regulatory requirements. The team also evaluated the DVA's use of supporting documents (e.g., permitting files, regulatory guides, and regulations), and equipment and instrumentation provided to the DVA inspectors for conducting inspections.

## b. Observations and Findings

The NHPP staff conducted 19 inspections of permittees during the review period. The inspections were routine inspections covering different types of permittees, including medical broadscope; medical institutions, written directive not required; medical institutions, written directive required; and research and development broadscopes. Inspection plans were generated by NHPP inspectors for each inspection and were reviewed and approved by the NHPP Director. The inspection team noted that the plans incorporated applicable NRC Inspection Procedures as described in the NRC Inspection Manual Chapter 2800, "Materials Inspection Program."

The inspection team observed that NHPP inspection reports appropriately documented those areas reviewed by the inspectors and that the inspection plans were followed in conducting the inspections. The inspection team also concluded that inspection findings were based on health and safety matters, and were well-founded and properly documented. The team noted that inspection reports were complete; that the inspection findings were reviewed by the NHPP Director, a good quality assurance practice; and that the reports were completed in a timely manner. The team also noted that NHPP inspectors were evaluated during an accompaniment by the NHPP Director at the proper frequency.

Each NHPP inspector was accompanied by an NRC inspector during the review period. The purpose of the accompaniment was to evaluate the technical quality of inspections being conducted by NHPP inspection staff. In addition, the NRC Project Manager accompanied the NHPP Director while the Director observed an inspection being conducted by one of his inspectors.

#### c. Conclusion

The team concluded that the licensee's inspection program was conducted in a manner that was compatible with the NRC's inspection policies, procedures, and guidelines. The team also concluded that NHPP inspectors were properly prepared for inspections, were provided with the necessary tools for conducting inspections, and conducted performance-based inspections in a manner that was consistent with NRC policies and procedures. Based on feedback from interviews with DVA inspectors, the team was informed that the NHPP Director's accompaniment of inspectors provided an opportunity for constructive feedback and added value to the inspection process.

## 4.0 Status of Materials Inspection Program

## b. <u>Inspection Scope</u>

The NRC inspection team reviewed the licensee's program for assigning inspection frequencies to permittees, and its timeliness in completing inspections based on inspection due dates. The team interviewed NHPP inspectors and management, and compared the licensee's inspection due dates posted in its tracking system against the actual dates that inspections were completed.

### c. Observations and Findings

The NHPP adopted NRC's inspection frequencies as defined in Temporary Instruction 33 for NRC Manual Chapter (MC) 2800, "Revised Materials Inspection Program," when the MML was issued on March 17, 2003. When MC 2800 was finalized by the NRC in November 2003, the priority for Program Code 2120 was changed from five years to three years. The team noted that the NHPP adjusted the priority of all of its permits that had a program code of 2120 from five years to three years. This resulted in approximately 17 permittee inspections that were then immediately overdue. A discussion with the NHPP Director indicated that the DVA's plan was to perform all of the overdue inspections by the end of calendar year 2004. All other inspections were completed by the required due dates.

#### d. Conclusion

The inspection team concluded that NHPP management appropriately assigned program codes and inspection due dates for its permittees, and that all inspections that were due during this six-month review period were completed in a timely fashion. Also, the team concluded that the licensee's plan to inspect the 17 overdue inspections that resulted from changes in MC 2800, was acceptable.

## 5.0 Technical Staffing and Training

### a. <u>Inspection Scope</u>

The NRC inspection team reviewed the licensee's radioactive materials program staffing level and turnover, as well as the technical qualifications and training history of the NHPP staff. In evaluating these elements, the team interviewed program management staff and reviewed the DVA training program, job position requirements, and casework related to licensing, compliance, and inspection.

## b. Observations and Findings

The NHPP personnel are assigned as headquarters-level staff reporting to the Chief of Patient Care Services. There have been no changes in the technical or administrative staffing of the NHPP since the first semi-annual review was completed in September 2003.

The NHPP is staffed with a director, five program managers, and administrative personnel. The director and one program manager are located in Little Rock, Arkansas. The remaining four program managers are located in the Eastern, Midwestern, Northwestern, and Southwestern United States.

The director of the NHPP continues to function as the communication link between the NRSC and program managers, and has sole signature authority for all permitting actions. However, each program manager is responsible for conducting independent technical reviews of permitting actions, resolving deficiencies with permittees, and forwarding completed reviews to the director for review and signature.

The director and program managers are all qualified to perform permitting reviews and conduct inspections. Additionally, each program manager is expected to develop expertise in specific assigned areas, e.g., there are specialists in the areas of decommissioning and high dose-rate remote brachytherapy. The administrative support staff are also cross-trained to perform all administrative functions.

The NHPP developed a written training program for its technical staff based on the requirements specified in NRC Inspection Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The program includes qualification journals and oral qualification boards. The NHPP has also developed a plan to complete all core training for its staff by calendar year (CY) 2006, pending availability of training courses. In addition to all technical staff completing NRC's "Fundamentals of Inspection" and "Licensing Practices and Procedures" courses, several staff have also completed training in root cause analysis and are scheduled to complete "Diagnostic/Therapeutic Nuclear Medicine" and "Teletherapy/Brachytherapy" training courses by the end of March 2004. Three of the five program managers have completed the course entitled "Inspecting for Performance." The other two program managers will be attending this course in CY 2005, as it is not scheduled for CY 2004.

# c. <u>Conclusion</u>

The inspection team concluded that the DVA has a well-balanced, sufficiently qualified staff to perform the regulatory duties of a master materials licensee. The team also concluded that the NHPP has successfully balanced the acquisition and scheduling of

staff training and management of the permitting and inspection workload, while successfully implementing a centralized control program.

## 6.0 Technical Quality of Permitting Program

## a. <u>Inspection Scope</u>

The NRC inspection team reviewed 22 DVA permitting actions completed by the NHPP program managers. Permitting actions were evaluated for completeness, consistency, proper isotopes and quantities authorized, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for permit actions. Casework was also evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authority. The permit files were reviewed for the retention of necessary documents and supporting data.

### b. Observations and Findings

The permitting casework reviewed by the inspection team was selected to provide a representative sample of all the permitting actions that were processed for DVA permittees during the six-month review period. The sampling included the following types of permits: medical broadscope, limited medical institution, and research and development broadscopes. The types of permitting actions selected for evaluation included 16 amendments to existing permits, five renewals, and one termination. No new permit requests or actions with potential significant environmental impact or complex decommissioning activities were processed during the review period.

Based on the review of the subject permitting casework, the inspection team concluded the NHPP staff followed appropriate NRC NUREGs, policies, procedures, and directives to ensure that the submitted information supported the permittee's request. The team noted that the technical reviews were complete and comprehensive, and that checklists were used for each type of permit program action reviewed. This resulted in consistency between the reviewers. Deficiencies identified were addressed in letters, e-mails and/or documented telephone conversations. The team also determined that deficiency correspondence contained appropriate regulatory language, was detailed, and provided the necessary information to support the action. All permitting actions were reviewed for technical content and signed by the NHPP Director. The actions were also forwarded to the NRC on a monthly basis.

#### c. Conclusion

The inspection team concluded that the NHPP staff processed permits in a manner consistent with NRC licensing policies, procedures, and guidance. In addition, the NHPP staff conducted quality technical reviews that were based on sound health physics practices.

#### 7.0 Status of Permitting Program

#### a. Inspection Scope

The NRC inspection team examined the licensee's permitting process to verify that permitting actions were handled and processed as described in the license. The team also evaluated the effectiveness of the licensee's tracking system.

### b. Observations and Findings

The NHPP is responsible for approximately 115 medical and medical/research permittees. All five regional NHPP program managers are authorized to review permitting actions, which are ultimately signed by the NHPP Director. Since the issuance of the MML on March 17, 2003, the NHPP has processed approximately 100 permitting actions. The NHPP did not receive any requests for new permits during this six-month review period. The program managers processed and/or completed all permitting actions well within the DVA's general timeliness goal of 30 calendar days.

The NHPP enters permitting action requests it receives from permittees into its Records Tracking Management System (RTMS). The RTMS is a system that is used to track casework status and is maintained in an electronic, centrally controlled file database. The actions are entered into the database, scanned, electronically filed, and archived. After processing by the administrative officer, the permit action requests are electronically provided to a program manager's office for review.

The RTMS also provides the NHPP staff access to documents supporting the permitting process (e.g., permit files, guidance criteria, inspection history, etc.). In addition, the tracking system provides NHPP staff with the capability to follow the status of any permitting action from start to completion. The inspection team also noted that information is readily retrievable from the system for staff use and program assessments.

## c. <u>Conclusion</u>

The inspection team concluded that the NHPP staff processed permitting actions in accordance with NRC approved procedures (SOPs). In addition, the inspection team determined that the process for reviewing and issuing permitting actions by the DVA was efficient, with timely issuances of permitting actions and a zero backlog.

### 8.0 Allegation and Incident Handling Programs

#### a. Inspection Scope

The NRC inspection team reviewed the DVA's program for handling allegations and responding to incidents. This included a review of all incidents (reportable and non-reportable) and allegations to determine applicability to NRC reporting requirements, the effectiveness of the DVA in handling allegations and responding to incidents, and the

status of any open allegations. The team also assessed communications between the NHPP and the NRSC to determine if allegations are communicated to the NRSC.

The team evaluated five cases documented in the licensee's event/incident files and tracking system for reportability requirements, and interviewed key licensee personnel involved with each case. These cases involved three instances where radioactive material originating from the VA permittees was discovered in landfills, and two medical events.

### b. Observations and Findings

The inspection team reviewed the details of each event involving radioactive material found in a landfill and determined that none of the events were reportable. One event involved non-NRC regulated material. A second event involved waste from a patient who had been treated with iodine-131 and was released from the VA Medical Center in accordance with 10 CFR Part 35. The third landfill event involved the inadvertent disposal by a permittee of two containers of medical waste: one containing thallium-201 (TI-201) (non-NRC regulated material), and the other containing technetium-99m (Tc-99m). The permittee, as required by the NHPP, conducted an investigation and determined that the amount of Tc-99m in the container was less than the reportable quantity as defined in 10 CFR Part 20.2201(a)(ii).

The DVA reported two medical events to the NRC during the six-month review period (September 2003 and March 2004). The first event occurred on December 29, 2003, and was identified by the NRC during an independent inspection at the VA Ann Arbor Medical Center on January 21, 2004. It was reported to the NRC by the NHPP on January 22. The licensee's 15-day written report was submitted on February 4, 2004. The referring physician was notified within 24 hours. The event involved a failure to administer a radiopharmaceutical in accordance with a written directive that prescribed 4.0 millicuries of strontium-90. The prescribing physician's intent was to administer strontium-89, which is what the technologist did in fact order and administer. The NRC issued a Severity Level IV violation to the DVA for failing to verify that the drug administered to the patient was as prescribed in the written directive (reference NRC IR 030-34325/2003-022(DNMS)).

The second medical event was identified by Boston VA Medical Center and reported to the NHPP on January 29, 2004. The NHPP reported the event to the NRC on January 30, 2004. The written report was submitted to the NRC on February 12, 2004, and the referring physician was notified within 24 hours of the discovery of the event. The event involved the administration of approximately 500 microcuries of iodine-131 to an elderly nursing home patient, instead of the prescribed 5 microcuries. On the same day that the event was discovered, the patient was administered potassium iodide (KI) to block uptake of iodine-131 by the thyroid. Preliminarily, the permittee calculated a committed dose equivalent (CDE) to the thyroid of approximately 86 rem, and does not expect the dose to have any adverse effect on the patient. The NHPP staff completed a reactive inspection (accompanied by NRC staff) on February 4, 2004, and are in the process of completing an assessment of the radiation dose to the patient. The NRC staff will continue to follow this case as the DVA completes its investigation and evaluates this event for safety and enforcement consequences.

The NHPP has not received any allegations since the first semi-annual review was completed. During the first semi-annual inspection, the inspection team identified that information regarding the receipt of an allegation by the NHPP from the NRC was forwarded to the NRSC chairman, but not to the rest of the NRSC membership. As a result of this finding by the inspection team in September 2003, the NHPP reported this allegation to the Committee at the October 2003 NRSC meeting. An NRSC working group was tasked to review the results of the NHPP's investigation, which indicated that the allegation was unsubstantiated. The working group plans to recommend that the allegation be closed at the next NRSC meeting scheduled for April 29, 2004.

#### c. <u>Conclusion</u>

The team determined that there were two reportable medical events during this review period. Both events were reported to the NRC in accordance with 10 CFR Part 35. The inspection team concluded that the DVA's program for responding to incidents was in compliance with the MML conditions and applicable NRC regulations and was being implemented effectively.

Regarding the DVA's allegation program, the inspection team noted that the DVA has almost completed its review of the allegation it received from the NRC in June 2003, and that DVA staff continue to process the allegation in accordance with the MML conditions.

### 9.0 NRC Independent Inspections of DVA Permittees

## a. <u>Inspection Scope</u>

During this six-month review period, the NRC conducted independent inspections of DVA permittees to assess the adequacy of their radiation safety programs and compliance with NRC regulations and the MML. The NRSC's corrective actions were reviewed for accuracy, completeness, timeliness, and effectiveness.

#### b. Observations and Findings

During the period from September 22, 2003 through March 4, 2004, the NRC conducted 14 independent inspections of DVA permittees. The NRC focused its inspections on programs with high risk radioactive materials applications, i.e., priority 2 and 3 programs, e.g., medical broad scope programs, etc. The NRC identified two Severity Level IV violations (reference NRC IR 030-34325/2003-022(DNMS)) and NRC IR 030-34325/2003-027(DNMS)), and one Severity Level III security violation (no civil penalty)(reference NRC IR 030-34325/2003-024(DNMS)).

The inspection team reviewed the licensee's immediate and long-term corrective actions for the violations and concluded that they were sufficient to address the issues and prevent recurrence.

#### c. Conclusion

Based on the overall results of the independent inspections conducted by the NRC, the inspection team concluded that permittee activities were conducted in a manner that protected the health and safety of its staff and the public.

#### 10.0 Exit Meeting

An exit meeting was held with DVA representatives on March 4, 2004. The overall scope and findings of the inspection were discussed. The DVA participants did not identify any information as being proprietary in nature.

#### LIST OF PERSONS CONTACTED

#### **Licensee Personnel**

- #A. Bierenbaum, Director of Safety and Technical Services
- #T. Holohan, M.D., Chief Patient Care Services Officer and NRSC Chairman
- #M. Hughes, Acting Associate Chief Patient Care Services Officer
- #M. King, Registered Nurse, Office of Patient Care Services
- \*E. Leidholt, Ph.D., Program Manager, NHPP Southwest Office
- K. Mayo, Information Technologist, NHPP Headquarters
- \*L. McGuire, Director, NHPP Headquarters
- J. McNew, Program Support Assistant, NHPP Headquarters
- \*L. Offutt, Administrative Officer, NHPP Headquarters
- M. Simmons, Program Manager, NHPP Northwest Office
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- \*A. Gaines, Sr. Health Physicist, Region IV
- \*K. Null, Sr. Health Physicist, Region III
- \*G. Shear, Acting Deputy Director, DNMS, Region III
- \*T. Simmons, Health Physicist, Region III
- \*Attended March 4, 2004, exit meeting #Attended March 4, 2004, exit meeting by telephone

In addition, numerous permittee staff were interviewed during the independent inspections conducted by the NRC during the review period September 22, 2003 through March 4, 2004.

### LIST OF ACRONYMS, ABBREVIATIONS

CFR Code of Federal Regulations
DVA Department of Veterans Affairs
IMNS Industrial and Medical Nuclear Safety
IP Inspection Procedures

LOU Letter of Understanding
MML Master Materials License

National Health Physics Program NHPP

Nuclear Materials Safety and Safeguards **NMSS** 

Nuclear Regulatory Commission NRC National Radiation Safety Committee NRSC

Quality Management Program QMP

Radiation Safety Officer RSO

Records Tracking Management System Standard Operating Procedure RTMS

SOP

Veterans Affairs VA